UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,690	01/09/2001	Orville G. Kolterman	030639.0066.UTL	4666

28381 7590 03/15/2006

ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/756,690	KOLTERMAN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,24-37 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,24-37 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/2/05 & 12/5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 05 December 2005 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/756,690 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's response filed on 05 December 2005 is acknowledged.

Applicant's amendment filed on 02 August 2005 is acknowledged and entered. Following the amendment, claims 16-18 and 38-40 are canceled, and claims 1, 10 and 24 are amended.

Currently, claims 1-15 and 24-37 and 41 are pending and under consideration.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 24-36 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Karpe et al. (Metabolism, 1999, 48:301-307), and in view of Beeley et al. (WO 98/30231), and Beers et al. (the Merck Manual, 1999, 17th edition, pages 200 and 2550), for the reasons set forth in the previous Office Actions mailed on 17 November 2004, and 06 June 2005.

Applicants argument, filed on 05 December 2005 has been fully considered, but is not deemed persuasive for reasons below.

At page 3 of the response, the applicant argues that, citing references, an obviousness rejection cannot be supported by the assertion that a reduction in food intake results in a lowering of triglyceride levels, that a reduction of food intake does not uniformly lower triglyceride levels, and that a teaching of reducing food intake does not inherently result in a lowering of plasma triglycerides. This argument is not persuasive because, as addressed in the last Office Action, besides discussing lowering of plasma lipids in the context of a reduction in food intake, Beeley also teaches that an exendin or an agonist thereof can be used for conditions or disorders such as obesity, diabetes, eating disorder, and insulin-resistance syndrome, for *lowering plasma lipids*, and for reducing the cardiac risk (page 10, lines 4-19). Although Beeley does not explicitly state that plasma lipids includes plasma triglyceride, applicants have ignored a very important fact that some of these conditions are well known to be specifically associated with the increased plasma triglyceride levels. For example, as addressed in the previous Office Actions, as evidenced by Beers et al. (the Merck Manual, 1999, 17th edition, page 2550, Table 296-4), it has been well established that diabetes is associated with an increase in triglyceride levels. Thus, it is instantly clear that Beeley's method of lowering plasma lipids with exendin for treating disorders such as diabetes would inherently lower the triglyceride levels.

At pages 2-3 of the response, the applicant argues that, citing more references, a teaching of lowering plasma lipids without more fails to teach or suggest the lowering of a particular subclass of lipids as individual classes of plasma lipids are differentially regulated, and differentially affected by lipid-lowering agents, and that the lowering of one class does not necessarily result in a reduction in another class. This argument is not persuasive because, while the examiner agrees that the lowering of one class does not necessarily result in a reduction in another class, it is not the issue in the instant case. In the instant situation, as addressed above, Beeley teaches the use of exendin for lowering plasma lipids in conditions known to be associated with the increased plasma triglyceride levels. Therefore, from Beeley's teaching, it is instantly obvious to a person having ordinary skill in the art that exendin can lower plasma lipids such as triglyceride.

At page 4 of the response, the applicant repeatedly (as in the previous responses) argues that the combination of cited references fails to teach or suggest each and every element of the claimed methods, that Karpe lacks any teaching or suggestion of lowering triglycerides in patients with elevated postprandial triglyceride levels using an exendin, and the remaining cited references fail to cure these deficiencies, and that the cited combination can provide neither motivation nor a reasonable expectation of success for modifying the teaching of the prior art to result in the claimed method. This argument is not persuasive for the reasons of record, and for the reasons above.

As addressed previously and above, the combined teachings of the cited references made the instant invention obvious as they teach that the postprandial elevation of plasma triglycerides is more closely linked to CHD (by Karpe), indicating the need of lowering triglyceride levels in these individuals; that exendin can be used for lowering plasma lipids in conditions such as diabetes (by Beeley); that plasma lipids encompass mainly cholesterol and triglyceride, and diabetes is associated with increased triglyceride levels (by Beers). As such, it becomes instantly obvious from the teachings of the prior art (nothing from applicants disclosure) that exendin can be used in patients having elevated postprandial triglyceride levels, and that a result as that confirmed by applicants is both inherent and expected.

Claims 15 and 37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Karpe et al. (Metabolism, 1999, 48:301-307), Beeley et al. (WO 98/30231), and Beers et al. (the Merck Manual, 1999, 17th edition, pages 200 and 2550), as applied to claims 1-14, 24-36 and 41 above, and further in view of Wagle et al., US 6,326,396 B1, for the reasons set forth in the previous Office Actions mailed on 17 November 2004, and 06 June 2005, and for the reasons above.

No particular argument in response to the instant rejection.

Conclusion:

No claim is allowed.

Advisory Information:

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
1/18/06

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600